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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,198	10/29/1999	DAVID ZAHNISER	CYM-034	6914
23639	7590	08/06/2003		EXAMINER
BINGHAM, MCCUTCHEON LLP THREE EMBARCADERO, SUITE 1800 SAN FRANCISCO, CA 94111-4067			KIM, CHONG R	
			ART UNIT	PAPER NUMBER
			2623	
			DATE MAILED: 08/06/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/430,198	ZAHNISER ET AL.
Examiner	Art Unit	
Charles Kim	2623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-22 is/are pending in the application.
  - 4a) Of the above claim(s) 15-19, 22 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14, 20 and 21 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 October 1999 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \*    c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4, 6-8</u> .	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-14, 20-21 are drawn to verifying a location of an area of interest, classified in class 382, subclass 128.
  - II. Claims 15-19 are drawn to a sample slide containing two datum marks, classified in class 359, subclass 396.
  - III. Claim 22 is drawn to determining a location of a datum mark in order to standardize the coordinate systems of two optical systems, classified in class 382, subclass 291.
2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case invention I can be used to verify the location of the area of interest with a slide that is different from the slide of invention II such as a slide that includes only one datum mark.
3. Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice

another and materially different process. (MPEP § 806.05(e)). In this case invention III can be used to locate a datum mark with a slide that is different from the slide of invention II such as a slide that includes only one datum mark.

4. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because invention III does not set forth the details of invention I. The subcombination (invention I) has separate utility such as identifying an area of interest.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with David Burse (Registration No. 37,104) on August 1, 2003 a provisional election was made without traverse to prosecute invention I, claims 1-14, 20-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-19 and 22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Drawings***

7. The drawings are objected to because they are not of sufficient quality for publication.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2, 5, 7, 10-14, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibbs, U.S. Patent No. 5,000,554 (“Gibbs”).

Referring to claim 1, Gibbs discloses a method for verifying a location of an area of interest within a sample, the method comprising the steps of:

- a. locating a datum (reference) mark on the sample (col. 9, lines 12-29)
- b. identifying the area of interest within the sample (col. 9, lines 30-41)
- c. determining the location of the area of interest relative to the mark (col. 9, lines 41-46)
- d. locating again the datum (col. 9, lines 60-66), wherein the location of the area of interest is verified if a dimensional error in locating the datum in step d relative to step a is less than a tolerance value (col. 10, lines 6-14). Gibbs explains that the exact location of the area of interest is determined depending upon the exact positioning of the datum (reference) mark in the beginning of the first inspection (step a) and at the beginning of the re-inspection (step d) [col.

10, lines 6-14]. The Examiner notes that determining the exact location of the area of interest is interpreted as verifying the location of the area of interest. Furthermore, the exact positioning of the datum mark in steps (a) and (d) results in a dimensional error value of zero. Therefore, the dimensional error is considered to be less than a tolerance value, since zero is less than any value.

Referring to claim 2, Gibbs further discloses that the step of identifying the area of interest within the sample comprises the step of optically scanning the sample (col. 9, lines 30-35).

Referring to claim 5, Gibbs further discloses that the sample comprises a cytological specimen deposited on a slide (col. 6, lines 20-22).

Referring to claim 7, Gibbs further discloses that the sample is mounted on a stage (col. 4, lines 54-58).

Referring to claim 10, Gibbs discloses a method for verifying a location of an area of interest within a sample, the method comprising the steps of:

- a. locating a datum (reference) mark on the sample (col. 9, lines 12-29)
- b. assigning a reference coordinate value to a location of the mark [col. 9, lines 16-20 and lines 38-46. Note that the position of the datum mark is assigned as the reference position (0, 0), since the x and y coordinates of the detected object is the coordinate position relative to the position of the datum mark, see also col. 2, line 47-col. 3, line 6]
- c. identifying the area of interest within the sample (col. 9, lines 30-41)
- d. assigning a coordinate value to the location of the area of interest (col. 9, lines 30-46)

e. spatially locating the mark (col. 9, lines 60-68), thereby determining the spatial offset value of the mark relative to the reference coordinate value, wherein the location of the area of interest is verified if the spatial offset value is less than a tolerance value. Gibbs explains that the exact location of the area of interest is determined depending upon the exact positioning of the datum (reference) mark in the beginning of the first inspection (step a) and at the beginning of the re-inspection (step e) [col. 10, lines 6-14]. The Examiner notes that determining the exact location of the area of interest is interpreted as verifying the location of the area of interest. Furthermore, the exact positioning of the datum mark in steps (a) and (e) results in a spatial offset value of zero. Therefore, the spatial offset value is considered to be less than a tolerance value, since zero is less than any value.

Referring to claim 11, Gibbs further discloses that the step of first locating the datum mark comprises the step of centering the mark in a field of view of an optical instrument (col. 9, lines 12-16).

Referring to claim 12, Gibbs further discloses the step of storing in the memory the coordinate value of the area of interest (col. 2, lines 40-46 and col. 6, lines 26-31).

Referring to claim 13, Gibbs further discloses the steps of:

- f. transferring the sample to a review station (col. 6, lines 41-47)
- g. locating the datum mark (col. 6, lines 47-52)
- h. setting a coordinate system of the review station based on a location of the mark (col. 6, lines 52-68, see also col. 3, lines 1-6).

Referring to claim 14, Gibbs discloses a method for verifying an area of interest within a cytological specimen on a slide loaded in an automated cytological imaging, the method comprising the steps of:

- a. placing the slide within an optical path of the imaging system (col. 9, lines 12-16)
- b. centering the datum mark on the slide within a field of view of the imaging system (col. 9, lines 12-16)
- c. assigning a reference coordinate value to a location of the mark [col. 9, lines 16-20 and lines 38-46. Note that the position of the datum mark is assigned as the reference position (0, 0), since the x and y coordinates of the detected object is the coordinate position relative to the position of the datum mark, see also col. 2, line 47-col. 3, line 6].
- d. storing in memory the reference coordinate value (col. 9, lines 16-20)
- e. scanning the slide to identify an area of interest within the sample (col. 9, lines 30-46)
- f. centering the area of interest within the field of view of the imaging system (col. 9, lines 38-41)
- g. assigning a coordinate value to the area of interest (col. 9, lines 30-45)
- h. returning to the reference coordinate value location (col. 9, lines 60-68)
- i. spatially locating the mark (col. 9, lines 60-68)
- j. comparing the reference coordinate value to a coordinate value resulting from step i, thereby determining a spatial offset value of the mark, wherein the location of the area of interest is verified if the spatial offset value is less than a tolerance value (col. 10, lines 6-14).

Gibbs explains that the exact location of the area of interest is determined depending upon the

exact positioning of the datum (reference) mark in the beginning of the first inspection (step c) and at the beginning of the re-inspection (step i) [col. 10, lines 6-14]. The Examiner notes that determining the exact location of the area of interest is interpreted as verifying the location of the area of interest. Furthermore, the exact positioning of the datum mark in steps (c) and (i) is analogous to comparing two equivalent coordinate values, wherein the resultant spatial offset value is zero. Therefore, the spatial offset value is considered to be less than a tolerance value, since zero is less than any value.

Referring to claim 20, see the rejection of at least claim 10 above. Gibbs further discloses an optical system and a stage movable relative to the optical system, at least one of the optical system and the stage being operable to position the sample in an optical path of the optical system (col. 6, lines 20-26).

Referring to claim 21, see the rejection of at least claim 5 above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs, U.S. Patent No. 5,000,554 (“Gibbs”).

Referring to claim 3, Gibbs fails to explicitly teach that the tolerance value is between about ten microns and one thousand microns. However, Gibbs explains that the location of the area of interest is verified when the dimensional error is zero (exact positioning of the mark), as noted above. Therefore, the dimensional error of Gibbs is still less than a tolerance value between ten microns and one thousand microns. Furthermore, the Examiner notes that the specific range of the tolerance value is not considered a patentable feature. For example, the specific range of the tolerance values would have been arbitrarily chosen by a user during experimentation, in order to meet his/her specific requirements for that particular experiment. Therefore, although Gibbs does not explicitly teach that the tolerance value is between about ten microns and one thousand microns, it would have been obvious to have a tolerance value between ten microns and one thousand microns in order to minimize the dimensional error, resulting in highly accurate locating and relocating of microscopic objects of interest in the sample slide (col. 12, lines 65-68).

Referring to claim 8, Gibbs fails to explicitly teach the step of rejecting the sample if the location of the area of interest is not verified. However, Gibbs is concerned with accurately locating and relocating the area of interest in the sample slide (col. 12, lines 65-68). Therefore, it would have been obvious to reject the sample if the location of the area of interest is not verified, since a location of the area of interest that is not verified implies that the area of interest is not accurately located. The ordinary artisan would have been motivated to do so in order to obtain sample slides that have the locations of the area of interest accurately determined, thereby improving the accuracy and efficiency of the examination process.

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10. Claims 4, 6, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs, U.S. Patent No. 5,000,554 ("Gibbs"), further in view of Kamentsky, U.S. Patent No. 5,587,833 ("Kamentsky").

Referring to claim 4, Gibbs fails to teach the steps of identifying a plurality of areas of interest within the sample and ranking the plurality of areas of interest in an order.

Kamentsky teaches the steps of identifying a plurality of areas of interest within a sample and ranking the plurality of areas of interest in an order (col. 8, lines 4-18).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Kamentsky's method saves time and increases efficiency of the re-examination process by providing the Pathologist with the locations of the areas of interest that were considered important during an initial examination (Kamentsky, col. 8, lines 22-39). Therefore, it would have been obvious to include the teachings of Kamentsky in the method of Gibbs, in order to reduce the redundancy of the work required by the Pathologist, thereby enhancing the efficiency of the overall examination process.

Referring to claim 6, Gibbs explains that the sample comprises a blood sample specimen (col. 6, lines 20-22), but fails to explicitly state that the area of interest within the sample comprises an abnormal cell. However, defining an area of interest within a blood sample as an abnormal cell was exceedingly well known in the art. For example, Kamentsky discloses that the area of interest within a blood sample comprises an abnormal cell (col. 1, lines 12-19).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Therefore, it would have been obvious to modify the area of interest of Gibbs so that it comprises an abnormal cell, as taught by Kamentsky, in order to utilize the

method for pathological research such as the examination of cancer cells, thereby increasing the flexibility of the system (Kamentsky, col. 1, lines 12-19).

Referring to claim 9, Gibbs fails to teach the step of placing a visible indicator proximate the area of interest identified within the sample.

Kamentsky teaches the step of placing a visible indicator proximate the area of interest identified within the sample (col. 8, lines 15-18).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Kamentsky's method saves time and thereby increases efficiency of the re-examination process by providing the Pathologist with visible indicators at the locations of the areas of interest that were considered important during an initial examination (Kamentsky, col. 8, lines 22-39). Therefore, it would have been obvious to modify the method of Gibbs, so that a visible indicator is placed proximate the area of interest within the sample, as taught by Kamentsky, in order to reduce the redundancy of the work required by the Pathologist, thereby enhancing the efficiency of the overall examination process.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. Graham et al. U.S. Patent No. 4,513,438 discloses an automated microscopy system that locates and relocates an area of interest in a sample slide by comparing the positions of datum markers to verify the location of the area of interest.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Kim whose telephone number is 703-306-4038. The examiner can normally be reached on Monday thru Thursday 8:30am to 6:00pm and alternating Fridays 9:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on 703-308-6604. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9314 for regular communications and 703-872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0377.

*CK*  
ck

August 5, 2003

*Jon Chang*  
Jon Chang  
Primary Examiner